

REMARKS

Claims 1 and 3-10 are pending in this application. Non-elected claims 3-5 and 7-10 have been withdrawn from consideration by the Examiner. By this Amendment, claims 1 and 3-9 are amended, and claim 2 is canceled. Support for the amendments to the claims may be found, for example, in the specification at page 4, line 12 to page 5, line 16, and in the claims as originally filed. No new matter is added.

In view of the foregoing amendments and following remarks, reconsideration and allowance are respectfully requested.

I. Personal Interview

The courtesies extended to Applicants' representative by Examiner Archie and Examiner Zeman at the interview held March 23, 2009 are appreciated. The reasons presented at the interview as warranting favorable action are incorporated into the remarks below, which constitute Applicants' record of the interview.

II. Claim Objection

The Office Action objects to claim 6 because "*Staphylococcus*" is misspelled. By this Amendment, claim 6 is amended to correct the misspelling. Accordingly, reconsideration and withdrawal of the objection are respectfully requested.

III. Rejection Under 35 U.S.C. §102

The Office Action rejects claims 1, 2 and 6 under 35 U.S.C. §102(b) as anticipated by EP 0786519 A2 to Kunsch et al. ("Kunsch"). By this Amendment, claim 2 is canceled, rendering its rejection moot. As to claims 1 and 6, Applicants respectfully traverse the rejection.

By this Amendment, claims 1 and 6 are amended to clarify that the methods of claims 1 and 6 are directed to "detecting a target bacteria as a member of the genus *Staphylococcus*

in a biological sample." By this Amendment, claims 1 and 6 are also amended to recite the specific members of the genus *Staphylococcus* that can be detected.

Thus, the methods of claims 1 and 6 require that they are able to detect any of the enumerated members of the genus *Staphylococcus*, and not just one or a few members of the genus *Staphylococcus*.

In contrast, Kunsch is directed to a single species of the genus *Staphylococcus*. Specifically, Kunsch is directed to "polynucleotide sequences of the genome of *Staphylococcus aureus*, polypeptide sequences encoded by the polynucleotide sequences, corresponding polynucleotides and polypeptides, vectors and hosts comprising the polynucleotides, and assays and other uses thereof." See Abstract.

Kunsch discloses polynucleotide sequences that "can be used as diagnostic probes or diagnostic amplification primers to detect the presence of a specific microbe in a sample, particular[ly] *Staphylococcus aureus*. Especially preferred in this regard are ORF[s] such as those of Table 3, which do not match previously characterized sequences from other organisms and thus are most likely to be highly selective for *Staphylococcus aureus*" (emphasis added). See page 10, line 52 to page 11, line 1.

Thus, Kunsch does not anticipate claims 1 and 6. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

IV. Rejection Under 35 U.S.C. §103

The Office Action rejects claims 1, 2 and 6 under 35 U.S.C. §103(a) as obvious over Kunsch in view of Sambrook et al., "*Molecular Cloning: A Laboratory Manual First Edition*," chapters 10, 11.12, 11.13 and 11.45-11.57 (1989) ("Sambrook"). By this Amendment, claim 2 is canceled, rendering its rejection moot. As to claims 1 and 6, Applicants respectfully traverse the rejection.

As discussed above, Kunsch fails to teach, and likewise fails to suggest, "[a] method for detecting a target bacteria as a member of the genus *Staphylococcus* in a biological sample" as claimed in claims 1 and 6, respectively. Sambrook, which is applied by the Office Action for teaching "the preparation of DNA probes and the conditions for hybridizations of oligon[u]cleotide probes," does not cure the deficiencies of Kunsch with respect to claims 1 and 6. See Office Action at page 7.

In addition, the methods of claims 1 and 6 rely on specific and sensitive amplification primers represented by SEQ ID NO:1 and/or SEQ ID NO:2. Upon contacting a target sequence indicative of a member of the genus *Staphylococcus*, these amplification primers are able to obtain amplicons with starting genomic DNA concentrations as low as 2×10^5 copies/ μ l. See specification at page 21, lines 20-26. The method is specific for each and every bacterial species of the genus *Staphylococcus* that was tested without any false positives for other tested bacterial species that are not of the genus *Staphylococcus*.

One of ordinary skill in the art could not have modified Kunsch to develop the methods of claims 1 and 6, specifically the specific and sensitive amplification primers required by claims 1 and 6, because species within the genus *Staphylococcus* differ considerably and Kunsch is solely directed to *Staphylococcus aureus*. See Kunsch at Abstract. For example, Kunsch discloses that "[t]he genus *Staphylococcus* includes at least 20 distinct species. [citation omitted]. Species differ from one another by 80% or more, by hybridization kinetics, whereas strains within a species are at least 90% identical by the same measure." See page 2, lines 7-10.

Thus, Kunsch in view of Sambrook would not have rendered obvious claims 1 and 6. Accordingly, reconsideration and withdrawal of the rejection are respectfully requested.

V. Rejoinder

Each of the pending claims have in common an amplification primer or probe comprising: (1) the nucleotide sequence set forth in SEQ ID No. 1; and/or (2) the nucleotide sequence set forth in SEQ ID No. 2.

Because the nucleotides sequences hybridize with consensus sequences found in all 35 members of the genus *Staphylococcus* recited in claims 1 and 6, all the claims share a special technical feature that defines a contribution over the prior art. That is, considering that species of the genus *Staphylococcus* differ from one another by 80% or more based on hybridization kinetics, hybridization primers and probes directed to all 35 members of the genus *Staphylococcus* recited in claims 1 and 6 with high specificity is not taught or suggested by the applied references discussed above. See Kunsch at page 2, lines 7-10. As such, Applicants respectfully submit that unity of invention exists between the claims and, thus, request withdrawal of the restriction requirement and rejoinder of the withdrawn claims.

VI. Conclusion

In view of the foregoing, it is respectfully submitted that this application is in condition for allowance. Favorable reconsideration and prompt allowance of this application are earnestly solicited.

Should the Examiner believe that anything further would be desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number set forth below.

Respectfully submitted,



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Attachment:

Petition for Extension of Time

Date: March 30, 2009

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